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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,127

09/25/2006

Akio Sugihara

Q97391

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EXAMINER

RAHMANI, NILOOFAR

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,127	Applicant(s) SUGIHARA ET AL.	
	Examiner NILOOFAR RAHMANI	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,10 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,10 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/10/2008 and 12/10/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-4, 6, 10, 12-17 are pending and claims 5, 7-9, 11 are cancelled in the instant application.

2. The rejection of claims 1-9 for “a range showing no influence on product stability” under 112, second paragraph is withdrawn in view of applicants amendment in paper dated on 11/03/2008.

3. *New Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 13-16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). These claims are withdrawn from consideration.

4. *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 6 are rejected because in the step (i), the term “a step of wet-granulation” is confusing. What are they doing with wet-granulation? Correction is required.

5. Claims 1, 4, 6 are rejected because in the step (ii), the term “reducing” is confusing. What are they reducing? What solution are they reducing? Correction is required.

6. Claims 1, 4, 6 are rejected because in the step (iii), the term “composition” is confusing. What composition is obtained? And how does it promoted? Correction is required.

7. Claim 2 is rejected because the term “amorphous”. There is insufficient antecedent basis for this limitation in the claim.

8. The rejection of claims 1-12 under obvious-type double patenting over Umejima et al., US 2008/0103171 is maintained. Applicants defer responding to the rejection and respectfully request that the rejection be held in abeyance. It is examiner's position that the rejection will be maintained for the reason of record.

9. The rejection of claims 10, 12 and 17 under 35 U.S.C. 102(e) over Slatter et al., US 2004/0138253 is maintained. Applicants argue that Slatter does not disclose, teach or suggest to existence of amorphous solifenacin or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formation. It is examiner's position that Slatter et al. disclosed the instant

claimed composition. The form of composition is silent in the prior art. Therefore, the solid form of the composition is inherently there.

10. The rejection of claims 10, 12 and 17 under 35 U.S.C. 102(e) over Fraser et al., US 2004/0198822 is maintained. Applicants argue that Fraser does not disclose, teach or suggest the existence of amorphous solifenacin or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formation. It is examiner's position that Fraser et al. disclosed the instant claimed composition. The form of composition is silent in the prior art. Therefore, the solid form of the composition is inherently there.

11. The rejection of claims 10, 12 and 17 under 35 U.S.C. 102(e) over saito et al., US 2005/0181031 is maintained. Applicants argue that saito does not disclose, teach or suggest to existence of amorphous solifenacin or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formation. It is examiner's position that Saito et al. disclosed the instant claimed composition. The form of composition is silent in the prior art. Therefore, the solid form of the composition is inherently there.

12. The rejection of claims 10, 12 and 17 under 35 U.S.C. 102(e) over Fraser et al., US 2005/0239890 is maintained. Applicants argue that Fraser does not disclose, teach or suggest the existence of amorphous solifenacin or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formation. It is examiner's position that Fraser et al. disclosed the instant

claimed composition. The form of composition is silent in the prior art. Therefore, the solid form of the composition is inherently there.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

01/14/2009

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625